Simply stated, "high compliance" and "blocking balloon" are recognized terms of art and neither of the applied references discloses or suggests either a high compliance balloon or a blocking balloon. As was pointed out during the interview, Nap discloses, quite explicitly, that the two balloons employed in a catheter according to the invention to which that patent is directed are, respectively, a balloon member 4 that is intended to be used for dilatation treatment and a balloon 5 that is to be used to position a stent. Specification, column 2, lines 21-23. Figure 2 of the patent drawing clearly shows that balloon 5, when inflated, will produce a force sufficient to dilate a blood vessel.

Similarly, Sahota discloses only dilatation, or low compliance, balloons. This reference states the following, at column 1, lines 11-15;

> More specifically, the present invention relates to dilatation catheters for use in administering treatments to relieve a stenotic region or to widen a constricted blood flow or tubular passage, such as the coronary artery, as well as other vessels.

As was discussed in detail during the personal interview, those who work in this art are well aware that there is a difference in kind between dilatation balloons, which include angioplasty balloons and stent placement balloons, on the one hand, and blocking, or occlusion, balloons, on the other hand.

In actual practice, a dilatation balloon must apply a substantial radial force to the wall of a blood vessel, sufficient to rupture the inner wall of the vessel, and this requires the use of a low compliance balloon that will undergo only a small degree of stretching as it expands against the blood vessel wall. In contrast, blocking balloons are used when a force sufficient to dilate the blood vessel wall is *not* to be created and for this purpose, use is always made of high compliance, or elastomeric, balloons that are capable of expanding in order to block the blood vessel without applying any significant radial force to the vessel wall.

High compliance balloons are made of a material that, due to its composition and thickness, allows them to stretch to a substantially greater degree than low compliance balloons.

Of course, a dilatation balloon, as it is expanded, will act to block the blood vessel wall. However, this does not mean that a dilatation balloon is a "blocking" balloon. All workers in this field recognize that the term "blocking balloon" has a quite specific meaning that does not include dilatation balloons. A medical practitioner intending to perform a procedure that involves the use of a blocking balloon would never employ a dilatation balloon; as a practical matter, it is simply not feasible to control the

inflation of a dilatation balloon so that it acts as a blocking balloon while not dilating the vessel wall.

During the interview, counsel presented to the Examiner a publication appearing on the website www.devicelink.com. A copy of that publication is enclosed herewith for the Examiner's information. Particular attention is drawn to the statements appearing on page 2 of that document that clearly demonstrate that, in this field, low-compliance balloons differ in behavior, and thus in structure, from high-compliance balloons. This page of the publication also clearly states that balloons employed for dilatation or angioplasty differ in kind from balloons employed for occlusion. This page of the publication also makes clear that low compliance balloons are manufactured in totally different ways from balloons used for occlusion. Indeed, this page of the publication makes the specific statement that "The two types have few similarities."

Thus, regardless of the manner in which a dilatation balloon *might, in theory,* be used, the fact remains that, in this field, there is understood to be a clear difference in kind between dilatation balloons, on the one hand, and blocking, or occlusion, balloons, on the other hand.

Further specific evidence of the differences in kind is provided by the attached declaration by the inventor who,

being a practicing cardiologist, is well qualified to present such a declaration.

In the Response to Arguments contained in the final Action of October 19, 2004, the Examiner appears to express the opinion that "high compliance" and "low compliance" are, somehow, arbitrary terms that do not imply any structural limitations. It is believed that the points discussed during the interview, as well as the information and evidence presented herein clearly demonstrate that such is not the case. Indeed, a logical conclusion of the reasoning presented in the last action (with which counsel disagrees) would be that any existing balloon can be considered to be either high compliance or low compliance! Such a conclusion would make the terms in question meaningless, despite the fact that they are considered to be significant in the field.

The fact is that a low compliance balloon must be made of a material having a different composition and/or thickness than a high compliance balloon because dilatation balloons and stent placement balloons must have physical and functional characteristics different from those of blocking balloons.

To reiterate, those skilled in the art would readily understand that the balloons disclosed in the applied references are not, and cannot be, high compliance blocking

balloons. Even if the balloons disclosed in these references have a higher compliance than some other, theoretical balloon, this does not make them high compliance balloons, as that term is employed in the art. It certainly does not mean that they can be considered to be blocking balloons, as that term is employed in the art, because blocking balloons are incapable of performing the functions of the balloons disclosed in these references.

The Examiner's attention is also drawn to a decision by the Federal Circuit in *Rowe v. Dror*, 42 U.S.P.Q 2d 1550 (1997). In that decision, the Court clearly held that the phrase "balloon angioplasty catheter" defines something other than a general purpose balloon catheter and that a patent for a general purpose catheter does not anticipate a claim for a balloon angioplasty catheter. By precisely the same reasoning, a patent disclosing only dilatation balloons cannot anticipate a claim defining a "high compliance blocking balloon".

During the course of the interview, the Examiner drew counsel's attention to U.S. Patent No. 5,833,657, which is also directed to catheters having balloons for dilatation and stent delivery. Column 3 of this patent describes a balloon having a low compliance at relatively low inflation pressures followed by a region of *higher* compliance at higher

inflation pressures. A compliance that is higher than low compliance is not necessarily a high compliance balloon. There is a clear difference, both in the English language and in the medical field, between a compliance that is higher than low compliance, on the one hand, and a high compliance, on the other hand. This depends on what those in the field understand to be a low compliance balloon and a high compliance balloon, and the understanding that does exist in the field has already been discussed in detail above. The balloons disclosed in this reference cannot be high compliance balloons because high compliance balloons cannot be used for dilatation and stent placement. This patent states, quite specifically, at column 3, lines 40-45, that even in the operating range where the balloon has a "higher compliance", it operates to further expand the blood vessel, or implant a stent. These functions cannot be performed by a high compliance blocking balloon.

In view of all of the foregoing, it is submitted that the limitation in claim 1 that one of the balloons is "a high compliance blocking balloon" clearly distinguishes over the disclosure contained in either of the applied references and hence is not suggested by any combination of the teachings of those references. To hold that those references disclose high compliance blocking balloons is simply to ignore all of

the knowledge existing in this field and the meaning of those terms to workers in this field. Therefore, such a conclusion is totally unjustified.

A number of the dependent claims further distinguish over the prior art. In this connection, attention is particularly directed to claim 5.

In view of the foregoing, it is submitted that the claims now in the Application clearly distinguish over the applied references and it is therefore requested that the prior rejection be reconsidered and withdrawn, that claims 1-10 be allowed and that the Application be found in allowable condition.

Note is also made at this point of the Examiner's agreement, during the interview, that if the present rejection is not withdrawn, she will be willing to discuss this matter directly with the inventor via telephone.

If the above amendment should not now place the application in condition for allowance, the Examiner is invited to call undersigned counsel to resolve any remaining issues.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By _____
Jay M. Finkelstein
Registration No. 21,082

JMF:dtb
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\D\Donm\DonMIchael 27\pto\AMD Response 18JAN05.doc